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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,042	07/22/2003	Remo Anton Hochstrasser	21272 US	1081
151 7590 01/06/2009 HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110				
EXAMINER SIEFKE, SAMUEL P				
ART UNIT		PAPER NUMBER		
1797				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/625,042

Applicant(s)

HOCHSTRASSER ET AL.

Examiner

SAM P. SIEFKE

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 provides a gel cutting containing a plurality of concentration points of different substances. No where in the specification is this limitation disclosed.

The Applicant points to paragraphs 2, 8, 12, 16 and 39 for teaching of a gel cutting containing a plurality of concentration points of different substances. Paragraph 2 specifically states that the gel layer may contain a mixture of substances that are separated to form concentration points. Nowhere does the specification state the actual gel cutting contain a plurality of concentration points of different substances. The Examiner disagrees with the Applicant's interpretation of paragraphs 8, 12, 16 and 39. Examiner notes that the amendment dated 3/12/07 first introduces the gel cutting containing a plurality of concentration points of different substances. Appropriate deletion of this limitation is required.

Claim 1 requires the physical distribution of the concentration points remain unchanged overtime. The specification is silent on "unchanged over time", The specification states the concentration points remain unchanged over a relatively long period (eight or more hours), this is different than the unchanged, i.e. forever.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 103(a) as being anticipated by WO 01/50121 (herein after WO '121) in view of Borresen (USPN 5,190,856).

WO '121 teaches a method for removing a gelatinous material that comprises the steps of separating a gel cutting from the gel by placing the cutter onto the gel layer (page 2, lines 29-31, fig. 3a-3d), placing the cut gel in a new container (page 3, lines 28-32, page 5, lines 7-9; fig. 3e) and covering the gel cutting with a processing solution (page 10, lines 11-20). WO '121 states the processing fluid is pre-filled within the multi-well processing plate 32 and the gel fragment is placed therein. It appears the gel

perimeter of the gel cutting is *approximately* equal to the perimeter of the new container (fig. 3e). Regarding the gel cutting containing a plurality of concentration points, WO '121 shows a further embodiment that allows for a single cutting tip 36 to make several cuts in a large band or plaque in order to excise the entire band or plaque before exchanging tips and subsequently excising a new band or plaque.

Regarding claim 2, as seen in figure 3a-3e, the gel 34 is cut and a portion is removed and placed in the processing well 32. The gel conforms to the inside of the processing well because it is smaller and takes the same contours of the well. Therefore the gel can be moved around within the processing well because there is a space between the gel and the sidewall of the processing well. As seen in fig. 3e the gel cutting can move in the gel holder 32 by an extent which is smaller than a predetermined maximum permissible deviation between a picking position in the gel cutting and the picking location in a picking device.

Regarding claim 3, WO '121 states that different sizes of cuttings can be cut out of the gel depending on the size of the spots, bands or plaques (page 10, line 33- page 11, line 9). If a larger spot were to be excised, the larger cutting would consume the entire space in the processing well 32 and would thereby be immovably disposed therein.

Regarding claim 5, WO '121 shows in fig. 3e a gel cutter (36) having a cutting edge with a contour which approximately corresponds to the contour of the chamber (inside gel holder 32) for receiving the gel cutting in the gel holder 32.

Regarding claim 6, separating a gel cutting from the gel by placing the cutter onto the gel layer is shown in fig. 3a-3d (page 2, lines 29-31).

Regarding claim 8, the Examiner is interpreting that when the gel is placed with in the processing plate containing the processing fluid, the gel is covered with the processing fluid after the gel is placed therein because the gel would sink or the user would submerge the cut gel so the processing fluid would cover the entire surface area of the cut gel.

WO '121 does not teach a gel cutting containing a plurality of concentration points of *different substances* or providing an equilibrating liquid over the gel cutting for a length of time sufficient to achieve an equilibrium degree of swelling of the gel cutting and thereby to ensure a constant degree of swelling of the gel cutting so that the dimensions of the gel cutting and thereby the physical distribution of the concentration points remains unchanged over time.

Borresen teaches a method for detecting single base mutations in DNA with denaturing gradient electrophoresis. The method comprises performing gel electrophoresis on a polyacrylamide agarose gel containing samples therein. After completion of gel electrophoresis the crosslinks in the gel are removed. A TS equilibrating solution (.4 M NaOH + .6M NaCl) is poured into a tray to cover the gel. After 30 minutes the TS solution is soaked off and a filter paper soaked in TS is placed on top of the gel. Blotting is performed in the TS equilibrating solution for 5-6 days. Borresen states electroblotting transfers only approximately 10% of the DNA, and will

also cause swelling of the gel making it difficult to compare the band patterns from each individual. The technique of Borresen using a polyacrylamide agarose mix and a reversible crosslinker in the PAG solves the transfer problem. After removal of the crosslink, the gels can easily be equilibrated with TS and no swelling occurs. Therefore, it would have been obvious to one having an ordinary skill in the art at the time of the invention to modify WO '121 to employ the TS equilibrating solution to the gel while blotting is performed so that minimum swelling occurs and the dimension of the gel cutting and concentration points remains unchanged over time. This will reduce swelling of the gel to a minimum and allow a user or visual device to compare the band patterns.

Regarding claim 7, it would have been obvious to one having an ordinary skill in the art at the time of the invention to modify the modified WO'121 to employ a TS equilibrating solution to the gel layer before cutting so the gel would not change in dimension before cutting. This will keep the gel cutting in its final dimension before and after cutting which would allow the bands to stay intact and not distort.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/50121 (herein after WO '121) in view of Borresen (USPN 5,190,856) as applied to claims 1-3 and 5-8 above, and further in view of Moi et al. (USPN 5,938,906).

WO '121 teaches a method for removing a gelatinous material and placing the cutting into a holder as seen above.

The modified '121 does not teach a clamping means to hold the cutting in the holder.

Moi teaches a casting cassette for gel electrophoresis that comprises clamps for holding the gel within the container (fig. 5a-5d). It would have been obvious to one having an ordinary skill in the art at the time of the invention to modify WO '121 to employ a clamp to hold the cut gel in the processing well to prevent the gel cutting from moving around in the container.

Response to Arguments

Applicant's arguments filed 9/26/08 have been fully considered but they are not persuasive. Applicant argues, "a gel cutting having a plurality of concentration points of different substances" is disclosed in the instant specification. The Applicant points to paragraphs 2, 8, 12, 16 and 39 for teaching of a gel cutting containing a plurality of concentration points of different substances. Paragraph 2 specifically states that the gel layer may contain a mixture of substances that are separated to form concentration points. Nowhere does the specification state the actual gel cutting contain a plurality of concentration points of different substances. The Examiner disagrees with the Applicant's interpretation of paragraphs 8, 12, 16 and 39. Examiner notes that the amendment dated 3/12/07 first introduces the gel cutting containing a plurality of concentration points of different substances. Appropriate deletion of this limitation is required.

Applicant argues, "Applicants have amended Claim 1 to reflect that the dimensions of the gel cutting and thereby the physical distribution of the concentration points remains unchanged over time. In other words, an equilibrium degree of swelling of gel cutting 27 is achieved and therefore its dimensions remain unchanged over time." Support for this amendment may be found throughout the specification generally, and in particular in paragraphs [0008] and [0012] of the specification." Claim 1 requires the physical distribution of the concentration points remain unchanged overtime. The specification is silent on "unchanged over time", The specification states the concentration points remain unchanged over a relatively long period (eight or more hours), this is different than the unchanged over time, i.e. forever.

Applicant argues, "The Examiner then alleges, on pages 6 and 7 of the outstanding Office Action, the above mentioned step b) would be obvious to one of ordinary skill in the art in view of the teaching of Borresen. However, even presuming arguendo that the Examiner's contentions have merit, the Examiner has implicitly acknowledged that step a) is not taught by either Minden or Borresen. Instead, Borresen is alleged to teach simply a TS equilibrating solution. Borresen does not teach, suggest or otherwise disclose step a) of Claim 1 and therefore Borresen fails to remediate the acknowledged deficiency of Minden concerning step a) of Claim 1. Since both Minden and Borresen individually fail to teach step a) of claim 1, Applicants respectfully submit that the combination of Minden and Borresen also does not teach step a) of Applicants' claimed invention." See rejection under 35 U.S.C. 112, first paragraph. Further the Examiner addressed the these limitations "Regarding the gel

cutting containing a plurality of concentration points, WO '121 shows a further embodiment that allows for a single cutting tip 36 to make several cuts in a large band or plaque in order to excise the entire band or plaque before exchanging tips and subsequently excising a new band or plaque.”

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAM P. SIEFKE whose telephone number is (571)272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/
Primary Examiner, Art Unit 1797